K100267

CORTEX

510(k) Summary for FlexiMarc

Cortex Manufacturing Inc.
621 SR 9 NE
PMB-B8
Lake Stevens, WA 98258

FEB 24 2010

Contact: Andrew Jones
Phone: (425) 334-2277

Preparation date: Feb. 23, 2010

Trade Name: FlexiMarc
Common Name: Implanted Marker
Classification Name: 892.5050

SE Device: Visicoil, RadioMed (an IBA Co.)

Brief Description:

FlexiMarc is an implanted marker used to identify the location of normal or diseased tissue for future treatments. The marker is placed at or near the treatment site and can easily be visualized in subsequent imaging studies. The location of the treatment area is then identified with respect to the marker.

The FlexiMarc soft tissue marker is fabricated of all biocompatible pure gold. It is available in varying lengths from 2 mm overall to 4 CM overall and ranges in diameter from 0.5 mm to 1.6 mm so that it can be identified in the varying medical imaging formats. FlexiMarc is delivered in sterile preexisting needles ranging from 20 GA to 16 GA.

FlexiMarc is intended for single use and is permanently implanted in the body. They are available pre-sterilized in accordance with FDA QSR sterilization procedures.

Intended Use Statement

In situations where the location of specific anatomy, normal and diseased needs to be marked for future procedures this device will serve as a surrogate locator. The all gold FlexiMarc is placed either in advance or during a treatment procedure. These all gold FlexiMarcs can be

visualized using medical imaging devices and they provide a reference from which the treatment can be guided.

Technological Characteristics

Both FlexiMarc and the predicate device are fabricated in such a fashion as to make them flexible in nature. This serves to reduce the potential for migration of the marker. It also provides a unique shape form which the treatment area can be identified.

Clinical Performance Comparison (Image Based)

Both markers have been imaged using the typical imaging devices including, CT, CBCT, MR, kV x-ray and MV x-ray both markers are visible in all of these modalities. Note: Diameter is a consideration with respect to MV x-ray imaging – meaning the larger diameter markers are required for both devices.

Conclusion

Both markers systems are deployed in the same fashion making this portion actually equivalent in its entirety.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

FEB 24 2010

Mr. Andrew Jones
Owner
Cortex Manufacturing, Inc.
421 S Davies Rd.
LAKE STEVENS WA 98258

Re: K100267
Trade/Device Name: FlexiMarc
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: January 28, 2010
Received: February 1, 2010

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100267

Device Name: FlexiMarc

Indications For Use:

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100267